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EXAMINER	
FUBARA, BLESSING M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/938,667	PETERSEN, JENS	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *129 and 131-147* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *129 and 131-147* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/30/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of amendment, remarks and IDS filed 7/30/09 and declaration under 37 CFR 1.132 filed 7/30/09 and 10/30/09. The examiner also acknowledges receipt of supplemental response filed 10/30/09. Claims 129, 141, 143 and 145 are amended. Claim 130 is canceled. Claims 129 and 131-147 are pending.

Power of Attorney

The examiner is looking into the statement filed under 37 CFR 3.73(b) on 12/23/08 and will inform the applicant regarding the status of the power of attorney.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn in view of the amendment to the claims (35 USC 112, first and second are withdrawn and the rejection of claims 129 and 131-147 under 35 U.S.C. 103(a) as being unpatentable over Vogel et al. (US 6,335,028) **is also withdrawn because Vogel does not teach the ratio of acrylamide to BIS at 150:1 to 1000:1).**

The Claims :

Claim 129 is drawn to method of treating urinary incontinence, the method comprises injecting "hydrogel that comprises about 0.5 to 25% by weight based on the total weight of the hydrogel," with the hydrogel having complex viscosity of about 2-50 Pas and elasticity modulus

of about 1-200 Pa; the hydrogel contains less than 50 ppm monomeric units and the polymer is prepared by combining acrylamide and methylene bis-acrylamide.

The recitation that the polymer is "the product of a method … bis-acrylamide," is the process of preparing the acrylamide hydrogel. It also noted that no specific amount of the acrylamide is recited. "Less than 50 ppm monomeric units" in the hydrogel represent residual amounts of the starting acrylamide monomer and the cross-linker methylene bis-acrylamide. The viscosity and the elastic modulus are inherent properties of the hydrogel or properties that are intrinsic to the hydrogel. The claim is also amended to say that the hydrogel product is made acrylamide is made by combining acrylamide and methylene bis-acrylamide in a molar ratio of 150:1 to 1000:1 and this recitation is also the process by which the hydrogel is prepared.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 129, 131-147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavlyk (US 5,798,096) in view of RU 2148957 or Vogel et al. (US 6,335,028) for reasons of record and with minor modification to address the amendment to the claims.

3. The claimed method of treating urinary incontinence comprises injecting the claimed composition into the urethra.

4. Pavlyk discloses cross-linked polyacrylamide hydrogel (claims 109, 110 and 123) produced from acrylamide and methylene bis-acrylamide monomers and apyrogenic or pyrogen free water (abstract; Table 1) meeting the limitations of the acrylamide hydrogels and pyrogen free water of the claims 129, 141, 135; the hydrogel is used as endoprosthesis by way of sterile injections into tissues by way of canals of the corporum cavernosum (column 1, lines 5-10; column 10, lines 37-56) meeting the requirements for injections. Pavlyk discloses that the hydrogel provides bulking (column 3, lines 17-18) meeting the characteristic and intended use of the composition of claim 129 that is injected into the urethra to treat urinary incontinence and the composition of Pavlyk would intrinsically impede flow of urine; the hydrogel of Pavlyk has low viscosity (column 2, lines 58-67) and the Pavlyk hydrogel would inherently have the viscosity and elasticity properties recited in claims 129, 134, 138, 139, 141. The amount of the acrylamide in the hydrogel ranges from 3.5 to 9.0% touching pints along the claimed acrylamide range of 0.5 to 25% as in the generic claims 129, 133, 141. The hydrogel of Pavlyk would intrinsically exhibit the intended use of the claimed hydrogel and would have the claimed properties since a product and its properties cannot be separated and thus meets claims 129, 134, 138 and 139. The 3.5% acrylamide of Pavlyk is less than 15%, 10%, 7.5%, 5% (meeting claims 129, 131-133, 141). The amount of water or aqueous solution in Pavlyk ranges from 88% to 96% (see Table 1) meeting the water limitation of at least 75% of claims 135 and 141 and Pavlyk's use of pyrogen free water meets the use of pyrogen free water in the claims 129, 135 and 141. Since the reaction between the acrylamide monomer and the methylene bis-acrylamide monomer cross-linking agent goes to completion, since the Pavlyk reference does not disclose the presence of residual monomeric units in the acrylamide hydrogel, and since the

residual monomer in the product is expected to be very minimal if any, Pavlyk renders less than 50 or 10 ppm monomeric unit obvious as in claims 129, 140. 141. With regards to the ratio of acrylamide to bis-acrylamide now included in claim 129 from canceled claim 130, Pavlyk does not report the ratio of the acrylamide to bis-acrylamide in terms of molar ratios but reports %amount of acrylamide used to % amount of bis acrylamide, but the ordinary skilled artisan in the field of acrylamide gels knows how to calculate molar amounts of bis-acrylamide in relation to molar amounts of acrylamide needed to form the desired polyacrylamide gel having the desired consistency in consideration that the bis-acrylamide being the cross-linking agent is generally used in amounts much smaller than the amount of the acrylamide. For example, Table 1 discloses the use of 3.5-9 g acrylamide and 0.01-1 g of BIS-acrylamide such that the artisan is capable of converting these amounts to mole form the molecular weight of acrylamide and BIS.

5. For claims 145 and 146, Vogel teaches including cells into the hydrogel and stem cell is a specific cell encompassed by generic disclosure of cells. For claim 147, it is the cells in the hydrogel that allows for cellular engraftment to the surrounding tissue so that when hydrogel containing cells is injected, claim 147 is met. Furthermore, 10, 2 and 6'clock are sections of the urethra as desired in claim 144 and the artisan has the technical knowledge of injecting the hydrogel into any of the sections of the urethra to achieve the expected goal of reducing urinary incontinence, and absent unexpected result, injecting into any of the sections as stated by claim 144 is not inventive over the prior art.

6. While Pavlyk discloses injecting the hydrogel into caverns, Pavlyk does not inject the hydrogel into the urethra. But RU reference 2,148,957 teaches that the polyacrylamide hydrogel, "a gel within the scope disclosed by Pavlyk" is injected into the ostium of the ureter to

impede the flow of urine (see paragraph of remarks filed 2/27/06 and first full paragraph on page 10 of remarks filed 10/08/07). Furthermore, Vogel treats urinary incontinence by injecting polyacrylamide hydrogel into the urethra (column 10, lines 40-45). Regarding claim 142, stress, reflex and urge incontinence are forms of urinary incontinence, and the submucosa is part of the urethra. Therefore, since treating urinary incontinence involves impeding flow of urine, taking the teachings of the Pavlyk, RU 2,148,957 and Vogel, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that injecting the hydrogel of Pavlyk into the urethra as taught by Vogel would impede urine flow and reduce the likely hood of incontinence.

Response to Arguments

7. Applicant's arguments filed 7/30/09 have been fully considered but they are not persuasive.

8. Applicant argues that Vogel does not suggest the use of the polymer of Pavlyk and that the Pavlyk polymer is used as a penile implant and that one of ordinary skill in the art would not substitute Pavlyk's polymer for Vogel's microparticles.

9. a) The examiner disagrees with the applicant that Vogel does not teach Pavlyk's polymer, the examiner also disagrees with applicant's interpretation of the rejection that the ordinary skilled artisan would not be motivated to substitute the Pavlyk's polymer for Vogel's for the reasons that follow: i) The references were not combined such that one polymer can be substituted for the other, rather Vogel is relied upon for treating urinary incontinence with hydrogel particles; ii) The Vogel prior art is not limited to the examples. While the examples use specific acrylamide, Vogel discloses that the hydrophilic acrylic monomer is acrylamide and

its derivatives, methacrylamide and its derivatives or hydroxymethylmethacrylate (column 7, lines 17-19). The acrylamide meets the limitation of acrylamide. iii) Vogel prepares the product for treating urinary incontinence by reacting hydrophilic acrylic monomer such as acrylamide and its derivatives, methacrylamide and its derivatives or hydroxymethylmethacrylate (column 7, lines 17-19) with N,N-methylene-bis-acrylamide, N,N-diallytartiamide or glyoxal-bis-acrylamide (column 7, lines 20-22) cross-linking agent. In general, the reaction between acrylamide and BIS-acrylamide results in a gel. iv) Vogel specifically refers to hydrogel particles (see Examples 6.1 and 6.2). Therefore, Vogel contemplates hydrogel particles. Thus, Vogel teaches same hydrogel as Pavlyk. However, Pavlyk was relied upon for teaching that hydrogel can be used to treat urinary incontinence by injection into the urethra and that the hydrogel can include cells for treating urinary incontinence.

10. Applicant argues that Vogel's polymer is in the form of a suspension of polyacrylamide microparticles and not a hydrogel as claimed.

11. b) The examiner disagrees with applicant's characterization of Vogel that Vogel's polymer is not a hydrogel because Vogel prepares the product for treating urinary incontinence by reacting hydrophilic acrylic monomer such as acrylamide and its derivatives, methacrylamide and its derivatives or hydroxymethylmethacrylate (column 7, lines 17-19) with N,N-methylene-bis-acrylamide, N,N-diallytartiamide or glyoxal-bis-acrylamide (column 7, lines 20-22) cross-linking agent. In general, the reaction between acrylamide and BIS-acrylamide results in a gel. Vogel specifically refers to hydrogel particles (see Examples 6.1 and 6.2). Therefore, Vogel contemplates hydrogel particles and thus discloses hydrogel. With regards to the Christensen reference and the difference between homogenous hydrogels and microparticles now presented

in the arguments, it is noted that Vogel anticipates the use of hydrogel particles and the claims have not recited homogenous hydrogels; the specification has not described what applicant means by homogeneous hydrogel now presented in the arguments. Thus, since Vogel contemplates hydrogel particles, the distinction between hydrogels and particles does not apply to the hydrogel particles of Vogel.

12. Applicant argues that Vogel does not teach or suggest combining acrylamide and methylene bis-acrylamide because Examples 6.1 and 6.2 disclose the use of methylolacrylamide or methylacrylamide derivatives.

13. c) The examiner disagrees. The Vogel prior art is not limited to the examples. While the examples use specific acrylamide, Vogel discloses that the hydrophilic acrylic monomer is acrylamide and its derivatives, methacrylamide and its derivatives or hydroxymethylmethacrylate (column 7, lines 17-19). The acrylamide meets the limitation of acrylamide of the claims. Vogel teaches the combination acrylamide and difunctional monomer that is N,N-methylene-bis-acrylamide, N,N-diallyltartiamide or glyoxal-bis-acrylamide (column 7, lines 20-22) with the N,N-methylene-bis-acrylamide meeting the limitations of the bis-acrylamide of the claims.

14. Applicant argues that Vogel's polymer content is from 27-100% by weight, while Pavlyk's is from 3.5-9%.

15. d) The examiner disagrees with applicant's reasoning to dismiss the rejections. v) applicant has not pointed to the section of Vogel that teaches 27-100% polymer. For Pavlyk, the percent content of polymer is as described above, namely, 3.5% to 9% acrylamide (Table 1), which is a species of the claimed generic range of 0.5-25%. Pavlyk was combined with Vogel

because Vogel teaches that acrylamide hydrogel is used to treat urinary incontinence, and therefore, the hydrogel of Pavlyk is capable of being used to treat urinary incontinence.

16. Applicant argues that Vogel discloses a range of 1.1:1 to 106:1 for the molar ratio of the acrylamide to the BIS while the claimed ratio is 250:1 to 1000:1

17. e) While Vogel may teach of ratio of 1.1:1 to 106:1, the examiner notes that Vogel was not combined with Pavlyk to teach ratios of acrylamide to BIS. It is further noted that, taking 3.5 g acrylamide and 0.01g BIS (see Table 1 of Pavlyk), the molar ratio of acrylamide to BIS would be at 3.5/71.1 divided by 0.01/54.2 (see applicant's calculation on pages10 of the response) = 759, that is a ratio of 759:1 for acrylamide :BIS and this ratio intersects the claimed range of ratio.

18. Applicant argues that the chemical composition of the Vogel microparticle is different from the Pavlyk hydrogel.

19. f) The examiner disagrees. The polymer compositions are the same in terms of the parts. The %parts may be different, but the combination is derived from Vogel's teaching that hydrogel composition is used to treat urinary incontinence such that the artisan would reasonably expect that the hydrogel of Pavlyk would be effective in successfully treating urinary incontinence.

20. The rejection of claims 129 and 131-147 was made using a combination of references and so far applicant has argued against the individual reference of Vogel, a secondary reference as though it is the primary reference, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

21. Applicant argues that Pavlyk teaches away from Vogel and that Pavlyk and Vogel do not teach the claimed hydrogel.

22. g) Pavlyk does not teach away from Vogel because both references teach the use of hydrogel and there is nothing in Pavlyk that says that the hydrogel cannot be used to treat urinary incontinence. Vogel is relied upon for teaching that cells can be included in hydrogels for treating urinary incontinence.

23. Applicant argues that Pavlyk and Sknar do not teach or suggest the recited hydrogel and that one of skill in the art would not generalize bulking agents for urinary incontinence.

24. h) The examiner agrees that Pavlyk and Sknar use hydrogel for bulking. But, the rejection did not generalize bulking agents for urinary incontinence. What was described in the rejection was that Sknar discloses that hydrogel that is within the scope disclosed by Pavlyk in injected into the ostium to impede urine flow. It is thus reasonable to expect that hydrogel used to impede flow of urine would be effective for treating urinary incontinence.

25. The examiner further notes that the rejection is not anticipatory, and it would be reasonable to expect that administering polyacrylamide hydrogel into the urethra would successfully provide that resistance needed to impede urine flow.

Declarations under 37 CFR 1.132

Applicant refers to the declaration by Dr. Diamond and Roger R. Dmochowski, both of which have been previously addressed. The content of the previous response was reproduced in the office action of 3/30/2009.

26. Applicant's arguments with respect to Dr. Diamond:

i) That Dr. Diamond's opinion with regards to pediatric urinary incontinence applies to adult incontinence. While this may be so, the opinion in the declaration stated that the skilled artisan would not have at the time the invention was made presume or reasonably expect that using bulking agent to correct vesicouretal reflux (VUR) would predictably be successful in treating pediatric urinary incontinence with "that bulking agent"," and the examiner responded to that statement saying that claims are not directed to treating urinary incontinence. The examiner further noted that the suggestion by the RU, the Sknar reference, and acceptance by the declaration that, bulking agents have been used to treat VUR and other types of urinary incontinence in children provides a basis for the ordinary skilled artisan to reasonable expect that bulking agents injected into the tube connecting the urinary bladder to the outside would successfully bulk the tube and increase resistance to the flow of urine from the bladder to the outside. The examiner did not say that the opinion of Dr. Diamond is flawed, but that when a declaration specifically centers on pediatric incontinence while the claims are not directed to treating pediatric incontinence, the opinion declaration did not appear to address the claimed subject matter. Furthermore, the rejection on record uses a combination of references to show that the process would have been obvious in view of the cited references that hydrogel has been known to be used in treating urinary incontinence so that the hydrogel of Pavlyk would be effective in treating urinary incontinence.

27. j) Applicant argues that Dmochowski recognizes that multiple references are used in the rejection but that Dmochowski says that one of ordinary skill in the art would not have generalized that the usage of bulking agent to treat UI. But, because injecting hydrogel into the

ostium impedes flow of urine, it is reasonable to expect that injecting hydrogel into the urethra would also impede flow of urine and thus treat urinary incontinence.

28. Two declarations were filed with the present response filed 7/30/09 and 10/30/09:

29. Roger R. Dmochowski filed 7/30/09:

30. The declaration under 37 CFR 1.132 filed 7/30/09 is insufficient to overcome the rejection of claims 129 and 31-147 based upon rejections under 35 U.S.C. 103(a) as being unpatentable over Pavlyk (US 5,798,096) in view of RU 2148957 or Vogel et al. (US 6,335,028) as set forth in the last Office in view of the discussion below:

31. Roger R. Dmochowski opines that the ostium and the urethra have different etiologies and the skilled artisan would not have expected that a "simple physical expediency" of introducing bulking agent into the urethra would have impeded the flow of urine as it related to "UI." The examiner appreciates the view of Roger R. Dmochowski as an expert in the area of "UI" in saying that it would not have been obvious to expect that hydrogel injection into the urethra would impede flow of urine just as the hydrogel impedes urine flow when injected into the ostium. But, since it is known in the art that hydrogel impedes urine flow when introduced into ostium, introduction of the hydrogel in other carverns or openings related/associated with the urinary tract would be expected to predictably impede flow of urine; it would have been reasonable at the time the invention was made to expect that introduction of hydrogel in any of the other openings associated with the urinary tract would successfully impede the flow of urine; further, the variation in the site of application would produce predictable resistance to urine flow.

32. It is further noted that Roger R. Dmochowski does not say that injection of the hydrogel into the urethra does not provide/constitute bulking.

33. Robert Lessel filed 10/30/09:

34. The declaration under 37 CFR 1.132 filed 7/30/09 is insufficient to overcome the rejection of claims 129 and 31-147 based upon rejections under 35 U.S.C. 103(a) as being unpatentable over Pavlyk (US 5,798,096) in view of RU 2148957 or Vogel et al. (US 6,335,028) as set forth in the last Office action in view of the discussion below:

35. Robert Lessel declares that Vogel's solid gel microparticles are not hydrogel because, microparticles are different from hydrogel, which is supported by the Christensen reference, that Vogel mentions myriad of potential monomers, that Vogel's microparticles must be cationic, that the Vogel does not teach hydrogel that comprises form about 0.5% to 25% polymer, that Vogel does not suggest a polymer that is a product of a method comprising combining acrylamide with methylene bis-acrylamide in a molar ratio of 150:1 to 1000:1, that the complex viscosity and the modulus of elasticity recited in the pending claims are not inherent in the polymer of Vogel.

36. The statements in the opinion declaration is not persuasive to overcome the rejections of claims 129 and 31-147 under 35 U.S.C. 103(a) as being unpatentable over Pavlyk (US 5,798,096) in view of RU 2148957 or Vogel et al. (US 6,335,028) because:

37. k) Vogel specifically refers to hydrogel particles and hydrogel particles must be hydrogel so that the distinction discussed by the Christensen reference does not apply to the hydrogel particles; l) Pavlyk teaches a ratio of 759:1 for the acrylamide:BIS and as such Vogel is relied upon for the teaching that hydrogels are used to treat urinary incontinence, and the Vogel art does not have to teach that ratio that is already taught buy Pavlyk; m) Because, the Pavlyk hydrogel comprises the claimed ratio of acrylamide and BIS, and the % amount of the polymer, the Pavlyk hydrogel would have the property of the claimed hydrogel since a product and its

properties cannot be separated, n) and Vogel described polymer obtained from hydrophilic acrylic monomer such as acrylamide and its derivatives, methacrylamide and its derivatives or hydroxymethylmethacrylate (column 7, lines 17-19) with N,N-methylene-bis-acrylamide, N,N-diallytartiamide or glyoxal-bis-acrylamide (column 7, lines 20-22) cross-linking agent, which does not represent myriad of potential monomers.

Secondary Considerations:

38. Applicant agues that applicant succeeded where no others have succeeded in that paragraph 8 of the Ankorina-Stark declaration filed 7/11/2008 states that polyacrylamide was considered unsafe or ineffective as a bulking agent; and that declaration by Diamond and Dmochowski state that the use of bulking agents was believed to be ineffective for the treatment of urinary incontinence. But while these declarations have been made, it is noted that Vogel has disclosed, before the invention was made, that hydrogels are used to treat urinary incontinence indicating that others have succeeded in using hydrogel to treat urinary incontinence; further, hydrogel is a known bulking agent according to Pavlyk and RU 2148957 and Vogel teaches the use of hydrogel in the treatment of urinary incontinence. Therefore, before the invention, others have successfully used hydrogel bulking agent to treat urinary incontinence.

39. Applicant also states that the combination of the properties recited allowed for the treatment of urinary incontinence. But, the recited properties as the word implies are properties and such properties are inherent to the hydrogel and before the invention, Vogel has used hydrogel to treat urinary incontinence and the composition of Pavlyk having acrylamide:BIS ratio intersecting the ratio in the range recited would also have the same properties such that one having ordinary skill in the art at the time the invention was made would be led to using the

hydrogel composition of Pavlyk to treat urinary incontinence since Vogel has taught that hydrogel is used to treat urinary incontinence before the invention. Therefore, others have succeeded before applicant.

40. No claim is allowed.

Suggestion:

It was suggested to applicant, as was suggested previously and as stated on page 8 of applicant's remarks of 10/20/06, that the hydrogel be injected into the urethra at 0.5 cm distally from the neck of the bladder to overcome the art, explanation of why that position provides unusual and unexpected result may be necessary. Please note that Vogel injects hydrogel into the urethra.

41. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618